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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/121,781	07/23/98	LAROSA G	LKS98-04

EXAMINER	
SALIMI, A	
ART UNIT	**PAPER NUMBER**
1648	17

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DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/121,781	Applicant(s) Larosa G. J.
	Examiner ALI R. SALIMI	Group Art Unit 1648

☒ Responsive to communication(s) filed on *12/26/00*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *Three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 5, 6, 8-12, and 45-106* is/are pending in the application.

Of the above, claim(s) *9-12 and 58-106* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 5, 6, 8, and 45-57* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *15*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

This is a response to the amendment B, paper No.6, filed 12/26/2000. Claims 2, 3, 4, 7, and 13-44 have been canceled. Claims 53-106 have been added. Claims 1, 5, 6, 8-12, 45-106 are pending. Claims 9-12 are directed to non-elected groups and have been withdrawn as previously stated. Newly submitted claims 58-106 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The chimeric antibodies, humanized antibodies, multiple variable compositions are distinct products and have distinct structure. The examination of all distinct groups would be highly burdensome.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-106 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. **Hence, Only claims 1, 5, 6, 8, 45-57 have been considered.**

Applicant is reminded to cancel the claims to the non-elected claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1, 5, 6, 8, 45-57 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lind et al (US Patent No. 6,084,075) on essentially the same ground as previously advanced in the Office Action mailed 9/19/00. Applicant contends that the mAb MCPR-02 is having a stimulating function and as a consequence does not anticipate the invention as amended. Applicant's argument as part of amendment B, Paper NO. 14, filed 12/26/00 has been considered fully, but they are not persuasive. At the onset applicant is reminded that the cited patent is presumed valid, and the claims of the cited patent are presumed valid. The Lind et al clearly disclosed the antibody directed to the amino-terminal region of CCR2 as designated by the mAb MCPR-02. This antibody is an agonist as shown in claim 1 of the ,075 patent. The agonist by definition is an agent that occupies a cell receptor. Hence, the MCPR-02 is directed to the same product as know claimed by applicants. The cited patent clearly taught that the antibodies showed great specificity for the human CCR2 in both flow cytometry and western blot analyses (see column 13 lines 43-48, and column 14, lines 1-7). In addition, applicant's interpretation of the MCPR-02 in Table III is misplaced. The said Table clearly shows that the MCPR-02 is exhibiting agonistic characteristic, hence, there should be no doubts that the said antibody is capable of inhibiting chemokine to CCR2 receptor. Still further, the claims clearly indicate that the antibody that is directed to amino terminal region will bind to CCR2 (see claims 1, and 2). As discussed before the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. The product disclosed in the above

cited patent appears to be identical to the product claimed by the applicants. Moreover, product taught by Lind et al would inherently exhibit the same affinity value and the disclosure clearly taught the potential therapeutic use of treating patients for wide variety of diseases such as rheumatoid arthritis etc... The rejection is maintained.

Claims 1, 5, 6, 8, 45-57 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Frade et al (J. Clin. Invest. 1997), on essentially the same ground as previously advanced in the Office Action mailed 9/19/00. Applicant asserts that the teaching of the cited reference is misleading . Applicant's argument as part of amendment B, Paper NO. 14, filed 12/26/00 has been considered fully, but they are not persuasive. Applicant admits on the record that the results taught by said reference could be due to actual antagonistic activity of the antibodies or to receptor desensitization. It is apparent that even applicant can not refute the fact that the antibodies disclosed by the cited reference could be antagonistic. As a consequence they are indeed anticipatory. They act the same as the one applicant is now claiming. There are no head to head comparison between the prior art products and the applicant's claimed antibodies, and the applicant's assertions are deemed as unsupported assertions. The rejection is maintained.

Claims 1, 5, 6, 8, 45-57 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Frade et al (J. Immunology, 1997), on essentially the same ground as previously advanced in the Office Action mailed 9/19/00. Applicant contends that the mAb MCPR-02 is having a

stimulating function and as a consequence does not anticipate the invention as amended. Applicant's argument as part of amendment B, Paper NO. 14, filed 12/26/00 has been considered fully, but they are not persuasive. The cited reference in Table 1 disclosed an antibody against CCR2 MCR-1R02 targeted against the amino terminal region of amino acids 24-38. The said antibody is the same or so similar to the antibody now claimed by the applicant that is indistinguishable. There are no head to head studies supporting the assertions made in the argument. The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, product taught by the cited reference would inherently exhibit the same affinity value. The rejection is maintained.

Claims 1, 5, 6, 8, 45-57 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Lind et al (WO 97/31949, 9/4/1997), on essentially the same ground as previously advanced in the Office Action mailed 9/19/00. Applicant contends that the mAb MCPR-02 is having a stimulating function and as a consequence does not anticipate the invention as amended. Applicant's argument as part of amendment B, Paper NO. 14, filed 12/26/00 has been considered fully, but they are not persuasive. The Lind et al clearly disclosed the antibody directed to the amino-terminal region of CCR2 as designated by the mAb MCPR-02. This antibody is an agonist as shown in claims 1, and 3. The agonist by definition is an agent that occupies a cell receptor. Hence, the MCPR-02 is directed to the same product as know claimed by applicants. The cited patent clearly taught that the antibodies showed great specificity for the human CCR2 in both

flow cytometry and western blot analyses (see page 23). In addition, Table III clearly shows that the MCPR-02 is exhibiting agonistic characteristic, hence, there should be no doubts that the said antibody is capable of inhibiting chemokine to CCR2 receptor. Still further, the claims clearly indicate that the antibody that is directed to amino terminal region will bind to CCR2 (see claims 1, and 9). As discussed before the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. The product disclosed in the above cited patent appears to be identical to the product claimed by the applicants. Moreover, product taught by above cited patent would inherently exhibit the same affinity value and the disclosure clearly taught the potential therapeutic use of treating patients (see page 10) for wide variety of diseases such as rheumatoid arthritis etc... The rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

2/12/2001

ALI R. SALIMI
PRIMARY EXAMINER